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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,371	10/05/2004	Hans-Ulrich Petereit	357546US0X PCT	8786

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EXAMINER

BERNSHTEYN, MICHAEL

ART UNIT	PAPER NUMBER
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1713

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/510,371

Applicant(s)

PETEREIT ET AL.

Examiner

Michael Bernshteyn

Art Unit

1713

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 03/27/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action follows a response filed on June 30, 2006. Applicants have amended claim 1, claims 19 and 20 have been added.
2. In view of the amendment, the rejection of claims 1-12 under 35 U.S.C. §§ 102 and 103 has been withdrawn.
3. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.
4. Claims 1-12 and 19-20 are active.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claim 1 recites: "does not contain transition metal complexes". This limitation was not described in the specification at all.

Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff'd mem.*, 738 F.2d 453 (Fed.Cir.1984).

6. Claims 11 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 19 recite the limitation "block polymerization". There is no such kind of polymerization, may be, Applicants meant "bulk polymerization".

Claim Rejections - 35 USC § 103

7. The test of this section of Title 35 U.S.C. not included in this action can be found in a prior Office Action.

8. Claims 1-12 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable as obvious over Haddleton et al. (U. S. Patent 5,804,632) in view of Rehmer et. Al (U. S. Patent 6,225,401).

With regard to the limitations of instant claims 1, 11 and 19-20, Haddleton discloses a production of an aqueous polymer emulsion comprises a low molecular weight polymer containing acid-functional groups made by using a free-radical polymerization process which employs a free-radical initiator and, for the purpose of controlling molecular weight, a transition metal chelate complex, wherein said low molecular weight polymer has a number average **molecular weight within the range of from 500 to 50,000** (abstract).

Typically the acid-bearing comonomers are olefinically unsaturated carboxyl-functional monomers such as mono carboxyl-functional acrylic monomers and olefinically unsaturated dicarboxyl bearing monomers; examples include **acrylic acid**, **methacrylic acid**, itaconic acid, maleic acid and fumaric acid (col. 5, lines 41-46). Non-acid functional monomer(s), which may be copolymerized with the acid monomer(s) include alkylmethacrylates and styrenes, and alkylacrylates can also be used, particularly if included as **comonomers** at low levels. Typically, the acid functional low molecular weight polymer is derived from a monomer system which contains **1-60 weight % of acid comonomer(s)**, and correspondingly **99-40 weight % of non acid functional comonomer(s)** (col. 6, lines 17-23). The low molecular weight polymer should have a number average molecular weight within the range of from **500-50,000**, preferably 700-20,000 and particularly 1,000-10,000 (col. 7, lines 8-10).

Haddleton discloses an aqueous emulsion polymerization process to form an aqueous emulsion of a hydrophobic polymer from at least one olefinically unsaturated monomer, wherein the low molecular weight polymer is introduced to the aqueous medium of said emulsion polymerization process before the start of and/or during said emulsion polymerization process and becomes dissolved or dispersed in said aqueous medium (abstract). The polymerization process can be carried out in the presence of a polymerization medium (acting as a **carrier medium** for the components and as a heat transfer medium) or in the absence of such a medium (i.e. in bulk) (col. 4, lines 21-24).

Rehmer discloses a process for producing readily filterable and deodorizable, highly concentrated, aqueous dispersions of pressure-sensitive adhesive, having readily

reproducible properties, on the basis of copolymers of esters of acrylic and/or methacrylic acid, by emulsion polymerization in the presence of customary emulsifiers and free-radical polymerization initiators in accordance with the monomer emulsion feed polymerization technique, in which the monomer emulsion is run in a feed stream into the polymerization reactor, which comprises conducting the emulsion polymerization of a monomer mixture comprising (A) at least 50% by weight of the overall monomer amount of at least one ester of acrylic and/or methacrylic acid with alcohols of 1 to 18 C atoms and (B) other olefinically unsaturated monomers (col. 2, lines 22-37).

Therefore, it would have been obvious to one having ordinary skill in the art when the invention was made to employ emulsion polymerization in the presence of customary emulsifiers and free-radical polymerization initiators in accordance with the monomer emulsion feed polymerization technique as taught by Rehmer in order to obtain the polymer composition comprising methacrylic acid units and alkyl esters of methacrylic acid units with low molecular weight as taught by Haddleton, to avoid the using of transition metal chelate complex, and thus to arrive at the subject matter of claim 1 and dependable claims 11, 19 and 20.

With regard to the limitations of instant claims 1 and 6-7, the combined teaching of Haddleton and Rehmer does not disclose that pH-sensitive polymer brings about at least 60% haemolysis at pH 5.5, and less than 5% haemolyses at pH 7.4, at a concentration of 150 g/ml in a cytotoxicity test with human red blood cells.

Regarding the pH-sensitive polymer's limitations in view of substantially identical monomers, their weight ratio, initiators (peroxide, redox, azo compounds, such as 2,2'-

Art Unit: 1713

azobis isobutyronitrile, etc.), emulsifier (sodium lauryl sulphate), process of aqueous emulsion polymerization producing such polymers and the same range of molecular weight (compare US'632, col. 12, line 7 through col. 17, line 18 and specification, page 14, line 15 through page 16, line 22) being used by Haddleton and Rehmer and the applicant, it is the examiner position to believe that the instantly claimed product, i.e. pH-sensitive polymer of Haddleton and Rehmer is substantially the same as pH-sensitive polymer recited in claim 1, even though obtained by a different process, consult *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

With regard to the limitations of instant claims 2-5, Haddleton discloses that methacrylates include normal or branched alkyl esters of C1 to C12, especially C1 to C10, alcohols and methacrylic acid, (i.e. C1 to C12, especially C1-10, alkyl methacrylates) such as **methyl methacrylate, ethyl methacrylate, n-butyl methacrylate** and lauryl methacrylate. Acrylates include normal and branched alkyl esters of C1 to C12, especially C1 to C10, alcohols and acrylic acid, (i.e. C1-C12, especially C1-10, alkyl acrylates) such as **methyl acrylate, ethyl acrylate, n-butyl acrylate** and 2-ethylhexyl acrylate (col. 5, lines 53-67). There is a mixture of MMA (methyl methacrylate), BMA (butyl methacrylate) and MAA (methacrylic acid) used for the preparation of the copolymer in LMP 10 (low molecular weight polymer) (col. 16 line 65 through col. 17, line 13).

Therefore all of the above methacrylates and acrylates are subgenus of non-acid functional monomers, which are generically disclosed, and which are polymerized with

acid monomer(s). Therefore, they can substitute each other. Additionally, according to the example of LMP 10, they can be employed singly or two or more monomers.

It is further noted that the amount of methacrylic acid, methacrylates and acrylates in the copolymer is a result effective variable, and therefore, it is within the skill of those skilled in the art to find the optimum value of a result effective variable, as per *In re Boesch and Slaney* 205 USPQ 215 (CCPA 1980). See also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382: "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."

With regard to the limitations of instant claims 8-10, it is worth to mention that these claims are intended use of pH-sensitive polymer and therefore it would have been known to one having ordinary skill in the art when the invention was made how to use the polymer composition in pharmaceutical industry.

Furthermore Haddleton discloses that one or both of the low molecular weight polymer and the hydrophobic polymer possess functional groups for **imparting latent crosslinkability to the composition** (i.e. so that crosslinking takes place e.g. after the formation of a coating therefrom). Alternatively, one or both polymers could carry functional groups such as hydroxyl groups and the composition subsequently formulated with a **crosslinking agent** such as a polyisocyanate, melamine, or glycouril; or the functional groups on one or both polymers could include keto or aldehyde carbonyl groups and the subsequently formulated crosslinker could be a polyamine or polyhydrazide such as adipic acid dihydrazide (col. 11, lines 10-27).

With regard to the limitations of instant claim 12, Haddleton does not disclose that molecular weight regulator is dodecyl mercaptan and/or 2-ethylhexyl thioglycolate.

Rehmer discloses that in the polymerization reaction it is also possible to add regulators, especially in amounts of up to 0.5% by weight of the amount of monomers, which reduce the degree of polymerization of the resulting **emulsion polymers**. Examples of such regulators are mercaptans, such as tert-**dodecyl mercaptan**, **ethylhexyl thioglycolate**, or 3-mercaptopropyltrimethoxysilane, or unsaturated compounds with allylic hydrogens, such as butenol (col.3, lines 31-38).

Therefore, it would have been obvious to one having ordinary skill in the art when the invention was made to incorporate dodecyl mercaptan and/or 2-ethylhexyl thioglycolate as molecular weight regulators for emulsion polymers as taught by Rehmer in order to obtain the polymer composition comprising methacrylic acid units and alkyl esters of methacrylic acid units with low molecular weight as taught by Haddleton, and thus to arrive at the subject matter of claim 1 and dependable claim 12.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Art Unit: 1713

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

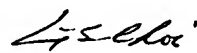
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bernshteyn whose telephone number is 571-272-2411. The examiner can normally be reached on M-F 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Bernshteyn
Patent Examiner
Art Unit 1713

MB
09/15/2006


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PRIMARY EXAMINER